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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/522,540 | 08/22/2005 | Peter Forsell | 2333-135 | 8492 |
| 23117 7590 08/25/2008 NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203 | | | | |
| EXAMINER | | | | |
| PRONE, CHRISTOPHER D | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 3738 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/522,540

Applicant(s)

FORSELL, PETER

Examiner

CHRISTOPHER D. PRONE

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SG/08)
Paper No(s)/Mail Date 1/27/05
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 40 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 40 requires that the base material is made from PTFE and depends from claim 28 that requires the filler material to be a gas. However the specification only enables gas filler to be used with a base material made from Teflon [0010].

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26 and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 26 and 37 require that the coating is on the inner surface of the tubing, but they both have dependency going back to claim 19 that requires the coating to be on surfaces exposed to aggressive body cells. The claim language of 19 infers that the

coating is on the outside of the implant otherwise the coating would not be exposed to the aggressive cells. Further clarification and amending is advised.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19-23, 25-29, 31, 33, 35-37, 41, and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuyava WO 01/67996 A2.

Kuyava discloses the same invention being an implant for use inside a human body comprising a tubular inflatable base with curved interior surfaces made of silicone coated in poly-para-eyylene or Parylene having a core filled with viscoelastic fluid. Kuyava further teaches the use of inflatable double walled cylinders with coatings on each layer

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 24, 30, 32, 34, 38, and 39 are rejected under 35 U.S.C. 103 as being unpatentable over Kuyava WO 01/67996 A2.

Kuyava discloses the invention substantially as claimed being described supra. However, Kuyava does not disclose the fluid filler materials.

Kuyava teaches that the features of penile prosthesis could be applied to breast implants (3:46-54). It is old and well known within the art of breast implants to use silicone gel as viscoelastic filler material.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the silicone gel as the filler fluid with the penile implant in order to enhance the viscoelastic properties of the device.

In regards to claim 34 Kuyava does not disclose the use of a second layer comprising polyurethane. In paragraph [0012] of the current application the applicant discloses that Elastic comprises is a commercially available material that comprises polyurethane and is used to coat implants. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the Elastic coating with the implant of Kuyava in order to enhance cell-barrier protection of the implant.

In regards to claim 34 Kuyava does not disclose the use of a second layer comprising polyurethane. In paragraph [0012] of the current application the applicant discloses that Elastic comprises is a commercially available material that comprises polyurethane and is used to coat implants. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the Elastic

coating with the implant of Kuyava in order to enhance cell-barrier protection of the implant.

In regards to claims 38 and 39 Kuyava does not disclose the use of a gas for filler material. It is old and well known that fluids, gases, and gels are interchangeable for use in filling implants. Ledergerber USPN 4,955,907 is a reference supporting that implants can use a variety of the filling materials such as fluids, gels, and gases.

. It would have been obvious to one having ordinary skill in the art at the time the invention was made to try gas to fill the implant of Kuyava in place of the fluid because they are known equivalents.

Claim 40 is rejected under 35 U.S.C. 103 as being unpatentable over Kuyava WO 01/67996 A2 in view of Timm et al. USPN 4,517,967.

Kuyava discloses the invention substantially as claimed being described supra. However, Kuyava does not disclose that the base member is made from PTFE

Tim teaches the use of PTFE for penile implants is old and well known in the same field of endeavor for the purpose of providing a flexible resilient implant.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the PTFE base material with the implant of Kuyava in order to provide a flexible resilient implant.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER D. PRONE whose telephone number is (571)272-6085. The examiner can normally be reached on Monday through Fri 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher D Prone
Examiner
Art Unit 3738

/C. D. P. /

/Corrine M McDermott/

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Supervisory Patent Examiner, Art Unit 3738